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APPLICATION NUMBER FILING DATE FIRST NAMED APPLICANT ATTORNEY DOCKET NO.

09/014,087 01/27/98 CARLYLE

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EXAMINER

QM12/0105

PETER S. DARDI, PH.D.  
WESTMAN, CHAMPLIN & KELLY, P.A.  
SUITE 1600-INTERNATIONAL CENTRE  
900 SECOND AVENUE SOUTH  
MINNEAPOLIS MN 55402-3319

ART UNIT PAPER NUMBER

9

DATE MAILED 07/38

01/05/00

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on Oct 12, 1999
- ☒ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-11, 14, 15, and 21-28 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-11, 14, 15, and 21-28 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(a).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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Claim 15 is objected to because of the following informalities:

The use of the phrase "said prosthetic heart valve comprises a porcine . . . " is confusing because the contents of the prosthetic valve was set forth in claim 14. Therefore, the Examiner suggests changing "comprises" to ---further comprises--- in order to overcome this objection.

Appropriate correction is required.

### *Drawings*

The drawings are considered to be informal because they fail to comply with 37 CFR 1.84(a)(1) which requires black and white drawings using India ink or its equivalent.

Photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(1) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(i), three sets of drawings or photographs, as appropriate, and, if filed under the provisions of 37 CFR 1.84(a)(2), an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

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The drawings are objected to because there is no detail discernable in the current photograph photocopies such that they do not aid in the examination of the application. Correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14, 21, 22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Noishiki (EP 0742020) wherein chemical binding as claimed can be non-covalent binding including ionic, van der Waals, etc. such that it reads on what is disclosed by Noishiki et al; see the whole document, especially Col 3, lines 32-34; Col. 7, line 42 to Col. 8, line 46 and see page 14, lines 18-22 which defines the meaning of "chemical binding" as used in the present claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-5 and 9-11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bayne et al (EP 0476983) alone.

Bayne et al anticipates the claim language wherein the artificial vessel as claimed is the fixed umbilical vein which would be allogeneic and crosslinked or fixed prior to coating covalently or noncovalently with proteins and growth factors; see the whole document, especially page 8, lines 14-26. The Examiner asserts that the coating of Bayne et al inherently must be some sort of non-covalent attachment of the molecule to the considered a coating by definition. Chemical binding is defined in the specification to include virtually any type of non-covalent binding; see page 14 of the present specification.

Alternatively, one could take the position that the umbilical vein is not necessarily allogeneic as set forth above or that the coating is not bound as claimed. However, the Examiner posits that the use of an allogeneic umbilical vein would have been considered at least obvious to one of ordinary skill because it would have lower antigenic reaction than one taken from a different species of animal. In addition, the coating of Bayne et al at least renders the binding of the coating clearly obvious to one of ordinary skill in the art.

With regard to claim 4 specifically, the linker molecule is the protein coating of Bayne et al which contains protein molecules which serve an attachment means or link to the underlying umbilical vein.

Claims 1, 2, 6, 7, 9-11, 14-15, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tischer et al (US 5,194,596) in view of Orton (US 5,192,312). Tischer et al

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discloses a transplant which is soaked in VEGF prior to implantation, but fails to disclose the form of tissue used such as allogeneic or xenogeneic tissue as claimed wherein the coating is inherently a chemical binding to the extent claimed or at least the carbopol acts as an adhesive to the extent claimed. However, Orton teaches that it was known to use allogeneic and xenogeneic heart valve tissue of porcine origin in similar growth factor treated tissues; see the whole document. Hence, it is the Examiner's position that it would have been obvious to use a xenogeneic or porcine heart valve tissue as the transplant tissue vascular graft of Tischer because of the high availability and low cost of such tissue.

Claim 8 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tischer et al and Orton as applied to claims 1, 2, 6, 7, 9-11, and 14-15 above, and further in view of Carpentier et al (US 4,648,881).

With regard to claim 8, both Tischer et al and Orton fail to disclose the use of bovine pericardial tissue for the tissue as claimed. However, Carpentier et al teaches that bovine pericardial tissue was known and used in the art to construct heart valves of reduced calcification; see the whole document, especially column 2, lines 56-67. Hence, it is the Examiner's position that it would have been obvious to use bovine pericardial tissue for the tissue of Tischer et al so that the chances for calcification formation would be reduced over the tissues of Tischer et al.

With regard to claims 23-28, both Tischer et al and Orton fail to disclose the use of crosslinked tissue as claimed. Carpentier et al, however, teaches that it was known to crosslink such implants with glutaraldehyde or leave them uncrosslinked in some cases; see Col. 3, lines 11-

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15. Hence, it is the Examiner's position that it would have been obvious to use a crosslinked tissue for the tissue of Tischer et al for the same reasons that Carpentier et al uses the same.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejections have provided rationale as to why the arguments are unpersuasive.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (703) 308-2672. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
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